

**PATENT****REMARKS**

Claims 1-9 and 12-22 are currently pending in this application. Applicants have amended claims 1-3 and 16 to place them in condition for allowance. Entry of this amendment and reconsideration are respectfully requested.

The Examiner rejected claims 16-22 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. More specifically the Examiner submits that claim 16 is inaccurate because the spiral track member does not engage the helix. Applicants have amended claim 16 to include an outwardly projecting follower member coupled to the helix that is slidably engaged by the spiral track member. Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 1-4, 7, 12-17 and 19-22 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,020,545 to Soukup. Applicants respectfully traverse this rejection.

Applicants' claimed invention, as recited in pending independent claims 1, 2 and 16 is directed to an implantable endocardial lead having a generally planar bulkhead member extending transversely of a longitudinal axis and located proximally of a helix in the retracted position and a guide system located proximally of the bulkhead member. (Underlining added for emphasis only). Thus, in applicants' claimed invention the bulkhead member is located between the helix and the guide system to substantially isolate the guide system from heart tissue thereby reducing potential helix jamming problems due to entrapment of heart tissue in the guide system as is commonly encountered in prior devices. Applicants respectfully submit that Soukup does not disclose or suggest the recited claim elements.

The Examiner points to the forward end 66 of the electrode body 54 of Soukup as a generally planar bulkhead member. However, the forward end of the electrode body of Soukup is located distally of the helix when the helix is in the retracted position and therefore is not between the helix and guide system as recited in applicants' claimed invention. Therefore, the alleged bulkhead member 66 of Soukup does not

**PATENT**

serve to substantially isolate the guide system from heart to tissue to mitigate the risk of jamming as provided by the present invention.

Applicants therefore respectfully submit that claims 1, 2 and 16 are novel and unobvious over Soukup and are allowable. Applicants further submit that claims 3-9 and 12-15 and claims 17-22 that depend from claims 2 and 16 respectively, are allowable as are claims 2 and 16 and for additional limitations recited therein.

The Examiner rejected claims 1-2, 7, 16-17 and 19 under 35 U.S.C §102(b) as being anticipated by U.S. Patent 4,624,265 to Grassi. Applicants respectfully traverse this rejection.

Applicants' claimed invention, as recited in pending independent claims 1, 2 and 16 is directed to an Implantable endocardial lead having a generally planar bulkhead member located proximally of the helix in the retracted position and a guide system located proximally of the bulkhead member... for rotating the helix about the longitudinal axis as the helix is moved between the retracted and extended positions. (Underlining added for emphasis only). Applicants respectfully submit that Grassi does not disclose or suggest the recited claim elements.

Rather, the electro-catheter of Grassi includes a body 21 housing a threaded pin 14 which is shaped in such a way as to shift rotatably by turning in a female thread 20 offered by the body 21. Rotational movement is produced by a stylet M having a distal key embodied such as to register with a corresponding socket 18 in the relative moving part, i.e. the threaded pin 14. (Grassi, col. 3, line 63 – col. 4, line 7).

Thus, in Grassi rotation of the stylet (M) causes the spiral anchor to project and 'corkscrew' into the cardiac muscle, thus ensuring mechanical fixture and electrical contact. (Grassi, col. 4, lines 20-24). Grassi does not however, disclose or suggest an endocardial lead having a guide system that rotates the helix about the longitudinal axis as the helix is moved between the retracted and extended positions as recited in applicants claimed invention. Neither does Grassi disclose or suggest a bulkhead member extending transversely of the longitudinal axis and located proximally of the electrically active helix in the retracted position.

Applicants therefore respectfully submit that independent claims 1, 2 and 16 are novel and unobvious over Grassi and are therefore allowable. Applicants further submit

PATENT

that claim 7 and claims 17 and 19 that depend from claim 2 and claim 16 respectively, are allowable as are claims 2 and 16 and for additional limitations provided therein.

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

6-15-04

Date

Pacesetter, Inc.  
15900 Valley View Court  
Sylmar, CA 91392  
818/493-2323  
818/362-4795 (fax)



Peter A. Nichols  
Registration No. 47,822  
Attorney for Applicant